



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,664	12/10/2003	Douglas T. Gjerde	P003.210	2157
55130	7590	10/02/2007		
PHYNEXUS, INC. 3670 CHARTER PARK DRIVE SAN JOSE, CA 95136			EXAMINER HYUN, PAUL SANG HWA	
			ART UNIT	PAPER NUMBER
			1743	
			MAIL DATE	DELIVERY MODE
			10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/733,664	Applicant(s) GJERDE ET AL.	
	Examiner Paul S. Hyun	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-11,15-20,23,25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 17-20,23,25 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-11,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,7-11,15-20,23,25 and 27-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/04, 5/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

REMARKS

The preliminary amendments to the claims and the Specification have been acknowledged. It is noted that claims 1, 8, 9, 15, 17-20, 23 and 25 were amended. Furthermore, claims 3-6, 12-14, 21, 22, 24 and 26 were cancelled by the amendments.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 7-11, 15 and 16, drawn to a capillary tube comprising an extraction surface, classified in class 422, subclass 69.
- II. Claims 17-20, 23 and 25-29, drawn to a method of conducting solid phase extraction using a capillary tube, classified in class 436, subclass 527.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus can be used to conduct immunoassays without desorbing the biomolecules of interest. An optical reading of the immobilized tagged molecules can be made through the transparent tube.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

Art Unit: 1743

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Sue Kalman on September 25, 2007, a provisional election was made with the preservation of traverse to prosecute the invention of Group I, claims 1, 2, 7-11, 15 and 16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-20, 23 and 25-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1743

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **1, 8, 9 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. (US 4,690,907) in view of Haase (US 5,276,062).

Hibino et al. disclose a silica capillary tube for conducting an immunoassay. The inside surface of the capillary comprises immobilized antibodies for binding an analyte of interest (see claim 1) wherein the antibodies can be specific for a virus or a protein complex (see columns 2-3). One end of the capillary can be connected to a vacuum pump to facilitate the pumping of liquid therethrough (see lines 20-25, col. 29). The capillary tube disclosed by Hibino et al. differs from the claimed invention in that Hibino et al. do not disclose that the capillary is coiled.

Haase discloses a capillary for conducting immunoassays wherein the capillary is coiled or spiral in shape (see lines 35-45, col. 3). In light of the disclosure of Haase, it would have been obvious to modify the shape of the capillary disclosed by Hibino et al. such that it is coiled. A coiled capillary would lengthen working surface of the capillary tube without increasing the length of the capillary tube.

Claims **2 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. in view of Haase as applied to claims 1, 8, 9 and 11, and further in view of Pentoney, Jr. (US 5,208,466).

Neither Hibino et al. nor Haase disclose a polyimide-coated capillary.

Pentoney et al. disclose a fused silica capillary tube for capturing tagged molecules and measuring the fluorescence of the molecules. The reference discloses that the integrity of the capillary can be strengthened by coating the external surface of the capillary with polyimide (see line 35, col. 3). The reference further discloses that a portion of the capillary can be uncoated to provide a path for a light source to enter the capillary (see line 65, col. 3-line 5, col. 4). In light of the disclosure Pentoney et al., it would have been obvious to one of ordinary skill in the art to coat the external surface of the modified Hibino et al. capillary with polyimide to strengthen it. It also would have been obvious to provide the modified capillary with a section that is uncoated so that fluorescence measurements can be made.

Claim **10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. in view of Haase as applied to claims 1, 8, 9 and 11, and further in view of Smith et al. (US 4,569,794).

Neither Hibino et al. nor Haase disclose the use of metal ions to bind analytes.

Smith et al. disclose the well-known method of immobilized metal ion affinity chromatography (IMAC) (see lines 5-20, col. 1). The reference discloses that IMAC uses immobilized metal ions to bind proteins. In light of the disclosure of Smith et al., it would have been obvious to one of ordinary skill in the art to use metal ions as the antibodies in the modified Hibino et al. capillary to bind proteins that have affinity towards the metal ions.

Claims **15 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. in view of Haase as applied to claims, and further in view of Miller et al. (US 3,807,389).

Neither Hibino et al. nor Haase disclose a syringe pump. However, it would have been obvious to one of ordinary skill in the art to replace the vacuum pump disclosed by Hibino et al. with any other pump capable of facilitating fluid movement within a capillary. Miller et al. disclose the use of a syringe to pump fluid through a capillary (see lines 35-40, col. 3). In light of the disclosure of Miller et al., it would have been obvious to substitute the vacuum pump with a syringe pump since syringes are widely available.

With respect to claim 16, it would have been obvious to one of ordinary skill in the art to provide a plurality of the modified Hibino et al. capillary tubes so that multiple assays can be conducted simultaneously. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), (holding that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.)


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
9/26/07


Jill Warden
Supervisory Patent Examiner
Technology Center 1700